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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,471	08/30/2001	Daryle Lee Petersen	11738.00029	3237

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EXAMINER	
WILLIAMS, CATHERINE SERKE	
ART UNIT	**PAPER NUMBER**
3763	7

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/945,471	Applicant(s) PETERSEN, DARYLE LEE
	Examiner Catherine S. Williams	Art Unit 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5,7-10,15,17,19-34 and 39-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *21-27 and 39-54* is/are allowed.

6)☒ Claim(s) *2-5,7-10,15,17,19-20 and 28-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The indication of allowable subject matter with regard to claims 15 and 17-18 has been withdrawn. A new rejection on the merits to those claims appears below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15, 17, 20, 28, 30-32 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Massengale (US Pat# 6,626,885).

Massengale discloses a catheter for uniform delivery of medication that includes either expressly or inherently the method steps of identifying the selected sites for delivering the therapeutic agent; selecting a catheter having a tubular section, the tubular section including a solid section and at least two diffusion sections (figure 6; three sections each including a port #356), the at least two diffusion sections longitudinally aligned from a distal end corresponding to the selected sites (see figure 16; longitudinal arrangement of three ports #356); and placing the catheter in the organism so that the at least two diffusion sections are placed at the selected sites. The tubular section further includes an outer wall and an inner wall, the outer wall having at least one opening (see figure 16; #356) within each of the at least two diffusion sections through to the inner tubular wall, the inner tubular wall lined with a microporous membrane (see figure 16). As

shown in figure 16, the outer surface of the microporous membrane has a interference fit with the inner surface of the tubular wall. The catheter is connected to a pump.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-4 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward (US Pat#s 5,713,923 and 5,978,702) in view of Elsberry (US Pat# 6,093,180).

Ward discloses techniques of treating epilepsy that include identifying the site (see 3:20-24), selecting at least one or two catheters with a microporous section (see 4:49-51), placing the catheters in the organism, coupling the catheters to a pump, and actuating the pump. See figures 1 and 6. Each end of the microporous sections is connected to an end of a solid catheter section. See figure 6. This would result in a solid cross section through any part of the distal region. The solid tube may be made from a radiopaque material (see 4:32-36). The pump may be implantable (see 4:46-48).

Ward fails to disclose a solid catheter tip. However, Elsberry which is incorporated by reference into both Ward patents discloses a solid catheter tip. A radiopaque marker tip (46) is shown in figure 4. The rounded surface (46) of the tip provides a profile for minimizing tissue disruptions during insertion.

At the time of the invention, it would have been obvious to incorporate the rounded solid tip of Elsberry into the invention of Ward. All three devices are analogous in the art and with the claimed invention; therefore, a combination is proper. Additionally, both Ward references incorporate by reference the Elsberry patent. Finally, the motivation for the incorporation would have been to provide the device of Ward with a rounded distal tip to minimize tissue disruptions during insertion in order to enhance the safety of the patient.

Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward (US Pat#s 5,713,923 and 5,978,702) in view of Elsberry (US Pat# 6,093,180).

Ward in view of Elsberry meets the claim limitations as described above but fails to include an external pump.

At the time of the invention, it would have been obvious to substitute the implantable pump with an external pump. Indwelling catheters with external pumps are well known in the art and are used in applications that require a large amount of fluid/drug infusions. The motivation for substituting an external pump would have been in order to broaden the application of the device to patients who require large volumes of drug infusion.

Claims 15, 17, 20, 28, 30-32, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al (US Pat# 6,350,253).

Deniega discloses a catheter for uniform delivery of medication that includes either expressly or inherently the method steps of identifying the selected sites for delivering the therapeutic agent (see 6:25; wound area); selecting a catheter having a tubular section, the

tubular section including a solid section and at least two diffusion sections (figure 6; three sections each including a port #56; see figure below), the at least two diffusion sections longitudinally aligned from a distal end corresponding to the selected sites (see figure 6; longitudinal arrangement of three ports #56); and placing the catheter in the organism so that the at least two diffusion sections are placed at the selected sites (see 4:25-28). The tubular section further includes an outer wall and an inner wall, the outer wall having at least one opening (see figure 6; #56) within each of the at least two diffusion sections through to the inner tubular wall, the inner tubular wall lined with a microporous membrane (see figure 6). As shown in figure 6, the outer surface of the microporous membrane has a interference fit with the inner surface of the tubular wall. The catheter is connected to a fluid reservoir (34) for both low and high pressure fluid delivery (see 9:60-63).

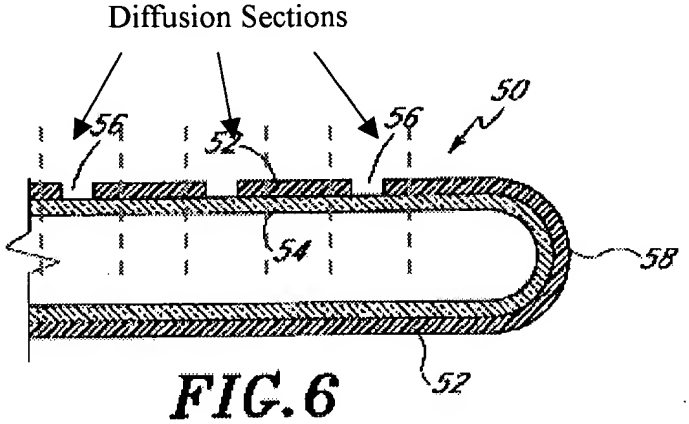

FIG. 6

Deniega fails to disclose coupling the catheter to a pump and actuating the pump. At the time of the invention, it would have been obvious to substitute a pump for the fluid reservoir of Deniega. Deniega does disclose that high pressure fluid may be introduced into the catheter and it is well known in the art to use externally placed pumps to create a high pressure fluid flow into

an indwelling catheter. In order to create a high pressure flow with the device of Deniega, as disclosed, the reservoir would either have to be raised in order to increase the effects of gravity or some external pressure would have to be exerted on the contents of the reservoir, e.g. compressed air. Substituting an externally placed pump would create this high pressure fluid flow (as desired by Deniega; see 3:37-41; 3:54-57 and 9:60-63) without additional manipulation to the reservoir. The motivation to substitute a pump for the reservoir would be an obvious design substitution in order to enhance the performance of the device by using a known part (pump) for the known function of that part (high pressurize fluid flow).

Claims 19 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al (US Pat# 6,350,253) in view of Ward (US Pat#s 5,713,923 and 5,978,702).

Deniega meets the claim limitations as described above but fails to include an implantable pump. However, Ward, as described above, includes an implantable pump (see 4:46-48).

At the time of the invention, it would have been obvious to substitute an implantable pump for the obvious pump of Deniega (as described above). It is well known in the indwelling catheter art that external pumps are cumbersome for active patients. Implantable pumps connected to indwelling catheters are well known in the art and are commonly used to enable a patient undergoing medical treatment (long term drug infusion) to be mobile. The motivation for substituting an implantable pump as taught by Ward would have been in order to provide a known solution for a known problem in the art.

Claim 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al (US Pat# 6,350,253) in view of Ward (US Pat#s 5,713,923 and 5,978,702).

Deniega meets the claim limitations as described above but fails to include an the solid tubular section comprising a radio opaque material. However, Ward, as described above, includes the tubular body having a radiopaque material (see 4:32-36).

At the time of the invention, it would have been obvious to incorporate a radio opaque material in to the tubular body of Deniega. Radio opaque catheters are well known in the art and are used in order to determine if an indwelling catheter is positioned in a desired treatment area of the patient's body. The motivation for incorporating a radio opaque material as taught by Ward would have been in order to increase the safety to the patient from a misplaced catheter.

Allowable Subject Matter

Claims 21-27 and 39-54 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke Williams CSW.
January 8, 2004